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15 February 2023

Via CM/ECF

The Honorable José R. Almonte, U.S.M.J.
United States District Court for the District of New Jersey
Frank R. Lautenberg Post Office Building and U.S. Courthouse
One Federal Square
Newark, NJ 07102

**Re: Metacel Pharmaceuticals, LLC v. Rubicon Research Private Limited
U.S.D.C.(D.NJ)
C.A. No. 2:21-cv-19463-EP-JRA**

Dear Judge Almonte:

We represent Rubicon Research Private Limited ("Rubicon") in the above matter. This letter responds to the letter of counsel for Metacel Pharmaceuticals LLC ("Metacel") regarding Rubicon's Motion for Summary Judgment.

In its letter, Metacel references Paragraph 34 of the Pretrial Scheduling Order. However, with respect to motions for summary judgment on non-infringement such as Rubicon's present motion Paragraph 35 displaces Paragraph 34 and is controlling. This was specifically discussed and negotiated at the Scheduling Conference (March 24, 2022 R. 16(b) Scheduling Conference Transcript, Tr. 9:1 – 16:6.)

Rubicon complied with Paragraph 35 when filing its Motion for Leave to File Motion for Summary Judgment on July 27, 2022. (ECF No. 39) At that time, Your Honor denied Rubicon's Motion for Leave without prejudice and stated the conditions required for Rubicon to file its Motion for Summary Judgment – completion of claim construction process and completion of document discovery. (ECF No. 53) These conditions have been met so Rubicon's Motion for Summary Judgment is procedurally proper.

Metacel has had Rubicon's Motion for Summary Judgment in its hands for longer than 6 months and there has been no changes to the bases for Rubicon's motion, as there have been and always will be three missing elements from Rubicon's ANDA Product that are non-optional essential elements of Metacel's patent claims.

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Everything Metacel has done since then (in fact before then, as Metacel has had Rubicon's ANDA for more than 1 year now and those missing elements are plain in the ANDA itself) has been to use the litigation process for an anticompetitive extension of its market protection.

The Hatch-Waxman Act was designed to provide a framework that balances the legitimate interests of branded pharm's innovation and patent protection, with the fundamental need for generic products to expeditiously made available to the American public. As such, the parties are required to expedite the litigation and the 30-month stay is not available if the patent is invalid, unenforceable or not-infringed. Where plainly non-infringed, as here, the system is not to be abused to extend branded's improper monopoly for its drug. Early motion for summary judgment, as originally recognized by the Court in setting the Scheduling Order, and as recognized by Your Honor in denying the Motion for Leave only until claim construction and document discovery was concluded, protects against such abuse.

Accordingly, Rubicon respectfully requests that Metacel's request to strike Rubicon's Motion for Summary Judgment be DENIED and that Metacel be finally required to respond to the Motion without further delay (or simply dismiss the case as it should have done upon receipt and first review of Rubicon's ANDA).

Respectfully yours,

A handwritten signature in black ink, appearing to read 'R. Touhey Myer', with a stylized, flowing script.

R TOUHEY MYER

RTM/rec

cc: All Counsel of Record (*via CM/ECF*)